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In re PATENT APPLICATION OF:

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PATENT APPLICATION

UTILITY PATENT

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TITLE OF INVENTION

Method and System for Centralized Medication Fulfillment

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CROSS-REFERENCE TO RELATED APPLICATIONS

The sole Inventor of the invention which is the subject of this application is also the sole Inventor of the following presently pending applications: Serial No. 10/657521 entitled Medication Delivery Device, filed with the United States Patent and Trademark Office on September 8, 2003; and Serial No. 10/690387, filed with the United States Patent and Trademark Office on October 21, 2003; and Serial No. 10/785903, filed with the United States Patent and Trademark Office on February 24, 2004; and Serial No. 10/787278, filed with the United States Patent and Trademark Office on February 26, 2004.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable

REFERENCE TO SEQUENCE LISTING, A TABLE OR A COMPUTER PROGRAM LISTING COMPACT DISK APPENDIX

Not Applicable

BACKGROUND OF INVENTION

This invention relates to a method and system for providing multiple medication products to a patient (including particularly for simultaneous ingestion or insertion into a live body by the patient) through a centralized medication product fulfillment facility, on an individualized, patient specific custom basis, in a cost effective, expedient manner which results in the maximization of medication intake compliance by the patient, with such simultaneous multiple medication approach being known as “synergy medication system”.

As used herein, the phrase “centralized medication product fulfillment facility” is sometimes referred to as “**CPMFC**”.

As used herein, the phrase “medication product” means, includes and encompasses, but is not limited to, prescription drugs, non-prescription drugs, over-the-counter drugs, and nutritional supplements.

As used herein, “order for medication product” means, includes and encompasses physician issued prescriptions and also patient initiated requests to purchase medication products which do not require physician issued prescriptions.

In the distant past, prescriptions issued by physicians were filled by pharmacists who actually compounded the prescription from raw materials at the pharmacy, using classic tools of mortar and pestle.

In more modern times, pharmacists most often instead “repackage” pills from large bottles and place small amounts of them in small bottles, affix a label and instructions, (or in certain instances, only re-sell pre-packaged medications without any direct contact with the unpackaged medications), and sell them to patients at substantially increased prices. In effect, to some extent the role of the pharmacist has evolved to become relatively clerical and non-discretionary.

During this same period of time, the cost the patient is charged for prescription medications has generally risen appreciably. This greater cost, coupled with the fact that many people are now living much longer than in the past, and need more medications, and often live on very limited resources, exacerbates the problem of high medications expenditures.

In addition, many patients, particularly older patients, are taking a wide variety of prescription medications. This is a result of both a higher quality of available health care available and more precise diagnostic tools.

The wide variety of medications taken currently by a typical patient creates for the patient the worrisome task of tracking and monitoring their intake of various

medications. This can be burdensome for some, and as a result many patients often do not take the correct medications on the correct schedule or in the correct amounts.

An objective of the present invention is to solve and remedy the problems described above.

One solution is to reduce cost by either eliminating the intermediary between the prescribing physician and the patient or by maximizing the efficiency of that said intermediary, thus enabling the said intermediary to share that resultant cost reduction with the patient.

An alternate solution is by decreasing the product cost by negotiating better, high volume arrangements with the source of the medication product.

As devices providing for the simultaneous delivery into a live body of multiple medication products, such as Multi-One™, become increasingly accepted in the marketplace, there will develop an increased competition among the pharmaceutical manufacturers to be participating providers of drugs, thus offering lower prices.

Also, since the devices providing for the simultaneous delivery into a live body of multiple medication products, such as Multi-One™, will deliver attractive patient-

friendly delivery systems, the focus will shift from single drugs to synergistic drug combinations and thereby increasing the therapeutic effects and long term health care cost efficient.

Examples of synergy medication combinations that could benefit from simultaneous delivery into a live body include (in addition to any individualized combination prescribed by the treating physician):

- (1) heart disease prevention: Omega 3 + statin + aspirin + Vitamin B complex;
- (2) diabetes treatment: Oral EX + Omega 3 + Anti-oxidants + statin + aspirin + Vitamin B Complex;
- (3) arthritis treatment: NSAIDS + Omega 3;
- (4) depression/anxiety: all neuroleptica + Omega 3 + Vitamin B complex;
- (5) hrt: estrogens + Omega 3 + Vitamin B complex + Calcium/Vitamin D;
- (6) contraception: hormone + Omega 3 + Vitamin B complex;
- (7) Parkinson disease: Dopamine + Omega 3 + Vitamin B complex;
- (8) Epilepsy: RS drugs + Omega 3 + Vitamin B complex;
- (9) General health: Multi-Vitamins + Omega 3.

The present invention also provides for a way for the intermediary between the prescribing physician and the patient to maximize that intermediary's efficiency by optimizing communications with the prescribing physician, and streamlining assembly and packaging of multiple medication products, including those sourced from multiple pharmaceutical manufacturers, thereby reducing operating costs and increasing medication taking compliance by the patient.

The centralized medication product fulfillment facility encompassed by this invention is a vehicle and mechanism which provides for the prompt delivery to a patient of multiple medication products in a form and through a manner resulting in maximized medication intake compliance by the patient and minimized cost to the patient.

BRIEF SUMMARY OF THE INVENTION

This invention relates to a method and system for providing multiple medication products to a patient (including particularly for simultaneous ingestion or insertion into a live body by the patient) through a centralized medication product fulfillment facility, on an individualized, patient specific custom basis, in a cost effective, expedient manner which results in the maximization of medication intake compliance by the patient.

Although the majority of said multiple medication products are drugs obtained through prescriptions issued by a physician, either in joint dosage with other prescription drugs or with non-prescription drugs, the invention also encompasses multiple medication products in situations in which none of the medication products are obtained through prescriptions from physicians but are patient orders for medication products which do not require prescriptions.

One embodiment of this invention is for a treating physician or physicians to electronically transmit to a CPMFC one or more prescriptions for an individual patient, with each such prescription being received electronically at the CPMFC from the prescribing physician, and with the CPMFC then assembling and immediately distributing either directly to patients, or in certain circumstances, to prescription "pick-up" facilities (such as retail pharmacies) located in proximity to

the patient, by overnight messenger delivery service in certain circumstances (such as Federal Express or UPS), or otherwise, of combination dosages of multiple medication products, which can be sourced from various points of origination and from various medication product manufacturers, with each such combination dosage of said medication products, which has been customized on a patient-by-patient basis, being contained within fewer containers than the number of prescribed medication products, which container(s) may be biodegradable when ingested, inserted or otherwise introduced into a live body.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a flow chart of one embodiment of the invention.

Fig. 2 is a flow chart of a second embodiment of the invention.

These Figs. 1 and Fig. 2 are not necessarily exhaustive of all embodiments of the invention.

DETAILED DESCRIPTION OF THE INVENTION

Embodiments of this invention of method and system of causing a physician sourced prescription of medication for an individual patient to be received at a centralized prescription medication fulfillment center, and for that prescription to be analyzed, verified, and filled for that individual patient in an automated production line type process, and for the individual patient prescription to then be virtually immediately dispatched, directly to the individual patient or to such other location as specified by the individual patient are essentially depicted and graphically portrayed in Fig. 1 and Fig. 2.

One embodiment of the invention is depicted in Fig. 1. After a patient visits a physician, or telephones a physician, and the physician forms a conclusion regarding the preferred treatment of that ailment of the patient, the physician prescribes medication or several medications to treat the ailment of the patient (101).

It need be noted that alternatives to the patient visiting or telephoning a physician encompass other communication mechanisms, including but not limited to internet or satellite or video conferencing.

That said medication prescription is then transmitted electronically directly by the treating physician (or support staff at his office, medical group or hospital where

he practices) to a centralized medication product fulfillment facility (103) for the purpose of that medication prescription being filled for the patient.

When received at the centralized medication product fulfillment facility, the prescription is electronically analyzed and verified, typically by a computer, at the centralized medication product fulfillment facility (105) in an effort to assure that the medication and the dosage and drug combination are proper and appropriate. After the appropriateness of the prescription is so confirmed at the centralized medication product fulfillment facility, the prescription is filled by computer directed automated packing production equipment (107). Promptly following the said filling of the prescription, the prescribed medication is dispatched from the centralized medication product fulfillment facility directly to the patient (109).

A second embodiment of the invention is depicted in Fig. 2.

A patient with an illness or affliction or other malady, or with the possibility of being at risk of developing an illness, affliction or malady, or with an interest in minimizing the risk developing an illness, affliction or malady, visits a physician, or telephones a physician (201).

It need be noted that alternatives to the patient visiting or telephoning a physician encompass other communication mechanisms, including but not limited to internet or satellite or video conferencing.

The physician examines the patient, or if by telephone (or other communications mechanisms, including but not limited to internet or satellite or video conferencing) interviews the patient, and forms an informed opinion and

conclusion, either immediately or after appropriate diagnostic tests or consultation with other medical specialists, regarding the illness, affliction or malady **(203)**. The said physician then determines the preferred treatment of the patient and the specific medication or medications to prescribe for use by the patient **(205)**. Obviously, the medications so prescribed, and the dosage or dosages of such medication(s), will depend upon numerous factors, all of which are considered by the physician in prescribing the said medications on an individualized, custom basis for each patient.

The said prescription documentation **(207)**, which can be in traditional paper format or can be in electronic format, includes the name and address of the patient, both to assure the identity of the patient and to assure that the proper patient is the recipient of the prescribed medication and also to provide a destination to which the prescription medication is to be dispatched when the prescription is filled. The said prescription documentation is preferably electronic, such as entered in or through an electronic "notepad" or voice recording of the prescribing physician **(215)**, or it can be non-electronic, such as a hand written prescription on a paper pad or a hand written file entry **(209)**.

If the said prescription is by electronic notepad **(215)**, that prescription is then transmitted electronically from the prescribing physician (including by his support staff at his office or group practice or hospital) to the centralized medication product fulfillment facility **(219)**. If the said prescription is by voice recording **(215)**, that voice recording is then transmitted or otherwise delivered to a computer which has speech recognition software and the oral voice recorded

prescription is then electronically converted into computer readable format **(217)**. Alternatively, the said voice recording could be transcribed by a computer input technician listening to the recording, and key-punching the prescription into a computer. The said electronic computer readable format prescription is then transmitted electronically from the prescribing physician (including by his support staff at his office or group practice or hospital) to the centralized medication product fulfillment facility **(219)**.

If the said prescription documentation is non-electronic **(207)**, such as a hand written prescription or a manual record or file entry **(209)**, it is then preferably transmitted to the centralized medication product fulfillment facility by e-mail or otherwise through the internet **(209)**, although it can also be transmitted to the centralized medication product fulfillment facility by telephone facsimile transmission ("fax") **(209)** or indeed even my overnight messenger deliver service (such as Federal Express or United Parcel Service) or even by United States Postal Service First Class Mail.

If the physician used non-electronic methods and or devices to memorialize the prescription **(209)**, the prescription set forth within non-electronic documentation by the physician can subsequently be transmitted to the centralized medication product fulfillment facility by having it optically scanned electronically into computer readable language at the physician's office, medical group practice or hospital **(211)**, and then transmitted electronically by e-mail or otherwise by internet to the centralized medication product fulfillment facility **(219)**.

Alternatively if the physician used non-electronic methods and or devices to memorialize the prescription **(209)**, the prescription set forth within non-electronic documentation by the physician can subsequently be transmitted to the centralized medication product fulfillment facility by telephone facsimile transmission ("fax") **(213)**, which by it's very nature converts the content of the non-electronic prescription documentation into computer readable format and language, with the said fax message being transmitted from the physician to an appropriate electronic device, such as a computer, located at the centralized medication product fulfillment facility **(221)**.

Upon receipt of the said prescription, in electronic computer readable format, at the centralized medication product fulfillment facility, a computer at the centralized medication product fulfillment facility reads the prescription and compares the prescription with a drug database to assure that the prescription has been properly read and interpreted by the computer at the centralized medication product fulfillment facility **(223)**.

If the centralized medication product fulfillment facility computer thus confirms that the said prescription has been has been properly read and interpreted by the computer at the centralized medication product fulfillment facility **(223)**, the said computer then compares the prescription with a drug database to assure that the dosages are within recommended limits **(225)**.

If the centralized medication product fulfillment facility computer thus confirms that the said prescription is within recommended limits **(225)**, the said computer then compares the prescription with a prescription database to assure that the

prescription drugs are not incompatible with each other or with other medications then currently prescribed to the same patient **(227)**.

In this regard it is noted that the centralized medication product fulfillment facility computer can search an appropriate database for other current prescriptions for the same patient issued by several different physicians, and if it locates any such current prescriptions for the same patient, and they are from different physicians, the centralized medication product fulfillment facility can determine by referring to appropriate data bases, whether the said multiple-sourced prescriptions are compatible with each other, if taken by the same patient during the same period of time.

If the centralized medication product fulfillment facility computer thus confirms that the said prescription is not incompatible with other medications then currently prescribed to the same patient **(227)**, then the said centralized medication product fulfillment facility computer directs the centralized medication product fulfillment facility packaging production equipment to proceed to fill the said prescription **(235)**.

If, however, upon receipt of the said prescription, in electronic computer readable format, at the centralized medication product fulfillment facility, a computer at the centralized medication product fulfillment facility is not able to assure that the prescription had been properly read by the computer at the computer at the centralized medication product fulfillment facility **(223)**, or is not able to confirm that the said prescription is within recommended limits **(225)**, or is not able to confirm that the prescription is not incompatible with other medications

then currently prescribed to the same patient **(227)**, then the centralized medication product fulfillment facility computer sends a message back to the prescribing physician for clarification and confirmation **(229)**. If the prescribing physician does not timely notify the centralized medication product fulfillment facility and confirm the uniqueness of the prescription as to the specific patient, the centralized medication product fulfillment facility computer notifies the patient that the prescription will not be filled **(231)** and the centralized medication product fulfillment facility processing of the prescription is terminated **(233)**.

However, if the prescribing physician does timely notify the centralized medication product fulfillment facility and confirms the uniqueness of the prescription as to the specific patient, then the said centralized medication product fulfillment facility computer directs the centralized medication product fulfillment facility packaging production equipment to proceed to fill the said prescription **(235)**.

Upon the centralized medication product fulfillment facility computer directing the centralized medication product fulfillment facility packaging production equipment to proceed to fill the prescription **(235)**, the centralized medication product fulfillment facility computer then determines whether the prescription is for one medication or for multiple medications **(237)**.

If the centralized medication product fulfillment facility computer determines that the prescription is for one medication **(237)**, said prescription is for one medication, the centralized medication product fulfillment facility computer then determines whether the prescription is for a liquid medication or a solid

medication **(239)**. The centralized medication product fulfillment facility computer then causes the centralized medication product fulfillment facility packaging production equipment to proceed to fill the prescription and package the filled prescription medication through appropriate computer directed packaging equipment and equipment programming **(243)**.

Alternatively, if the centralized medication product fulfillment facility computer determines that the prescription is for multiple medications **(237)**, said prescription is for one medication, the centralized medication product fulfillment facility computer then determines whether the prescription is for liquid medications or solid medications or both **(241)**. The centralized medication product fulfillment facility computer then causes the centralized medication product fulfillment facility packaging production equipment to proceed to fill the prescription and package the filled prescription medication through appropriate computer directed packaging equipment and equipment programming **(243)**.

With the centralized medication product fulfillment facility packaging production equipment, having thusly **(243)** been directed by the centralized medication product fulfillment facility computer to fill the said prescription, the centralized medication product fulfillment facility computer then causes the printing of the appropriate label for the said prescription medication **(245)**. The said label(s) can include, for example, patient name, address, age, medication content, identifier [such as color or shape] and usage directions **(245)**.

The thusly printed label **(245)** is then affixed to the packaged prescription medication **(243)**, as depicted at **(247)**.

The prescribed medication so packaged and labeled are then subjected to appropriate quality control procedures **(249)**.

If the said packaged and labeled prescribed medication is approved by the said quality control procedures **(249)**, the said packaged and labeled prescribed medication is then addressed, using addressing equipment, for delivery in accordance with instructions included with the prescription **(207)** as received at the centralized medication product fulfillment facility from the prescribing physician **(221)**, either to the patient directly or to an intermediary for pick-up by the patient **(253)**. In this regard, although delivery directly to the patient is generally the most expedient delivery mechanism, there are situations and circumstances as to which delivery to an intermediary is preferable, such as to a retail pharmacy at which related products would also be available, or to a hospital or convalescence facility at which the patient may be confined and at which control over medications taken by a patient is necessary.

If the said packaged, labeled and addressed medication **(253)** is to be sent by the centralized medication product fulfillment facility directly to the patient **(253)**, the said addressed medication package is then prepared and processed for dispatch from the centralized medication product fulfillment facility **(257)**.

Alternatively, if the said packaged, labeled and addressed medication **(253)** is to be sent by the centralized medication product fulfillment facility to an intermediary on behalf of the patient, then the centralized medication product fulfillment facility computer causes the patient to be notified of the dispatch of the medication to the intermediary **(255)**, and the said addressed medication package is then

prepared and processed for dispatch from the centralized medication product fulfillment facility (257).

The said packaged, labeled and addressed medication can be dispatched by the centralized medication product fulfillment facility either for express delivery or for non-express delivery (257).

If the said dispatch is to be by express delivery, the said medication package is then dispatched by the centralized medication product fulfillment facility by overnight messenger delivery service, such as Federal Express or United Parcel Service (259).

Alternatively, if the said dispatch is to be by non-express delivery, the said medication package is then dispatched by the centralized medication product fulfillment facility by United States Postal Service, First Class Mail (261).

With regard to the centralized medication product fulfillment facility packaging production equipment referred to in the second embodiment described herein, if the prescription is for a non-liquid single medication, but including liquids contained within liquid gel caps, the prescription can be filled by an automated packaging production line in which the prescribed pills, capsules or gel caps are removed from relatively large containers and are electro-mechanically deposited into a small container.

Similarly, if the prescription is for a liquid single medication, the prescription can be filled by an automated packaging production line in which the prescribed liquid medication is from relatively large containers and is electro-mechanically

deposited into a small container. Furthermore, if the prescription is for multiple non-liquid medications but including liquids contained within liquid gel caps, the prescription can be filled by an automated packaging production line in which the various prescribed pills, capsules or gel caps are removed from the respective relatively large containers and are electro-mechanically deposited into several small containers.

Alternatively if the prescription is for multiple non-liquid medications but including liquids contained within liquid gel caps, the prescription can be filled by an automated packaging production line in which the various prescribed pills, capsules or gel caps are removed from the respective relatively large containers and are electro-mechanically deposited into numerous individual dosage containers (such as one-portion sized zipper closure type bags, or blister packages), with each such individual dosage container holding the several medications which the patient is to take at the same time, with the appropriate drug label affixed to each such individual drug container; the said individual dosage container may (or may not) itself be constructed of a material which is itself biodegradable when ingested or inserted into a live body.

Further alternatively, if the prescription is for multiple non-liquid medications but including liquids contained within liquid gel caps, the prescription can be filled by an automated packaging production line in which the various prescribed pills, capsules or gel caps are removed from the respective relatively large containers and are electro-mechanically deposited into numerous blister pack cards or substrates or portion thereof, with each such blister card or substrate or portion

thereof to hold one individual dosage of each of the several medications which the individual patient is to take at the same time, with the appropriate drug label affixed to each such individual drug container.

Again further alternatively, if the prescription is for multiple non-liquid medications, the prescription can be filled by an automated packaging production line in which the various prescribed medications had been reformulated to be in pill form, with each such pill to be of a standardized color, size and shape (for both ready identification and to facilitate handling) for a specific medication a specific unit dosage amount, with said pills having been designed specifically to be insertable into a specific standardized capsule-type outer container, which capsule type container is itself intended to be ingested or inserted into a live body, and to be biodegradable when inside of a live body, with the appropriate drug label affixed to each bottle or other "bulk" container into which the said capsule type outer containers are automatically inserted and packaged at the central facility.

Although the embodiments described above are for multiple medication products which are drugs obtained through prescriptions issued by a physician, either in joint dosage with other prescription drugs or with non-prescription drugs, the invention also encompasses multiple medications, none of which are obtained through prescriptions from physicians but are non-prescription drugs, including nutritional supplements.

It is recognized and understood that the above described embodiments of the invention are illustrative only, and that this invention is not to be regarded as limited in any way or to any extent to the embodiments disclosed herein, but is to be limited only by the Claims set forth herein.